

Remarks

*Claim Rejections - 35 USC § 102 (e)*

The Examiner rejects claim 1 as being anticipated by Zhang et al. USPN 6,302,874. The Examiner states that "Zhang et al. teaches the application of electrical energy in the form of electroporation pulses simultaneously applied with ultrasound (see column 9, lines 46 - 47) along with ascorbic acid to enhance collagen production."

Claim 1 has been amended to ensure that the limitations already presented in the preamble are held to be limiting. Amended claim 1 now reads:

A process for the stimulation of production of extracellular dermal matrix proteins in human tissue which comprises simultaneously delivering to said tissue ultrasound and electrical energy in an amount sufficient for the stimulation of production of extracellular dermal matrix proteins in said tissue.

Zhang et al. relates to use of electroporation-mediated *topical delivery of agents*, such as Vitamin C (emphasis added) (col. 1, lines 13 - 17). Zhang does not teach simultaneously delivering to tissue ultrasound and electrical energy in an amount sufficient for the *stimulation of production of extracellular dermal matrix proteins* in the tissue, as claimed in claim 1 (emphasis added).

The particular passage referenced by the Examiner (column 9, lines 46 - 47) teaches that, "the invention method optionally further comprises applying vibration to the skin surface in combination with an electrical impulse *to topically introduce a composition into the skin* (emphasis added) (col. 9, lines 41 - 44). Zhang et al. does not teach the simultaneous delivery of

ultrasound and electrical energy for stimulation of production of extracellular dermal matrix proteins.

Applicant, therefore, respectfully requests reconsideration of the Examiner's rejection of claim 1, which has been amended. Applicant further requests allowance of claims 2 - 13, each of which at least indirectly depends from claim 1.

*Claim Rejections - 35 USC § 103*

*Zhang et al. (alone or alternatively in view of Alvarez et al.)*

The Examiner rejects claims 14 - 16 as being unpatentable over Zhang et al. alone or alternatively in view of Alvarez et al.

The Examiner states that, "While Zhang et al. teaches the application of ascorbic acid to wounds in the background of the invention, he does not teach the application of his electroporation/ultrasound method to a preexisting wound. However, the examiner considers it obvious to have applied the method to a wound that was created by injury since his method deals with healing the skin via collagen formation. Alternatively, to have produced a wound in the skin to test the healing capabilities of the Zhang et al. method would have been obvious in view of the teachings of Alvarez who induces keratome wounds in test animals for purposes of testing the collagen synthesis capabilities of his method."

Claim 14 has been amended to ensure that the limitations already presented in the preamble are held to be limiting. Amended claim 14 now reads:

A process for the stimulation of the natural healing processes in human skin tissue which comprises creating a wound in the dermal layer of said skin tissue and

thereafter simultaneously delivering to said skin tissue ultrasound and electrical energy in an amount sufficient to stimulate natural healing processes in said skin tissue.

As stated above, Zhang et al. deals with “a method for cosmetic delivery of L-ascorbic acid-containing compositions to the layer of skin wherein collagen formation takes place to enhance production of collagen and thereby combat some of the effects of aging and oxy-radical damage on the skin (Abstract).” Zhang et al. claims a method of delivery of a compound, not a method to deliver ultrasound and electrical energy in an amount to stimulate natural healing processes. Zhang et al. neither teaches or suggests simultaneously delivering to said skin tissue ultrasound and electrical energy in an amount sufficient to stimulate natural healing processes in said skin tissue as claimed in amended claim 14. Consequently, applicant requests allowance of amended claim 14 over Zhang et al.

With regards to the combination of teachings of Zhang et al. and Alvarez, Alvarez teaches that “the proliferative and/or migratory capacity of epithelial and connective tissue cells involved in repair and regeneration can be affected by an electrical field.” Alvarez has no teaching related to the “simultaneously delivering to said skin tissue ultrasound and electrical energy”.

Further, There is no teaching or suggestion to combine the teachings of Zhang et al. which teaches a method for cosmetic delivery of L-ascorbic acid-containing compositions to the

layer of skin with Alavarez, which teaches affecting with an electrical field the proliferative and /or migratory capacity of epithelial and connective tissue cells involved in repair.

Neither Zhang et al. nor Alvarez, either alone or in combination, teach creating a wound in the dermal layer of skin tissue and thereafter simultaneously delivering to said skin tissue ultrasound and electrical energy in an amount sufficient to stimulate natural healing processes in said skin tissue as is claimed in amended claim 14. Applicant, therefore, respectfully requests reconsideration of the Examiner's rejection of claim 14.

*Claim Rejections - 35 USC § 103*

*As applied to claims 16 - 18, above, and further in view of Eppstein et al. USPN 5,445,611*

The Examiner rejects claims 17 - 20, and 22 - 28 as unpatentable over as applied to claims 16 - 18 above, and further in view of Epstein et al.

The Examiner states that, "Applicant differs in reciting specific parameters regarding the application of the phonophoresis such as frequency as well as intensity. Applicant's parameter's are well known as demonstrated in column 3, lines 30 - 45. The selection of applicant's phonophoretic parameter range would have been obviously employed in the Zhang et al. device since they are merely conventional parameters known in the phonophoresis art. Similarly, applicant has shown no special improvement in his electrical energy pulsing (claim 20) and would therefore be mere routine experimentation to discover the pulsing schemes that work for Zhang et al's electroporation."

Claims 17 - 20 and 22 - 28 each depend, at least indirectly, from claim 14, which is submitted to be patentable. Claims 17 - 20 and 22 - 28 are submitted to be patentable for at least this reason.

Regarding claim 20, the Examiner states that, "applicant has shown no special improvement in his electrical energy pulsing." Applicant respectfully directs the Examiner to page 8, lines 12 - 15, which state:

This is an automatic adjustment of pulse frequency from about 5 pulses per second to about 105 pulses per second, then back to about 5 pulses per second and so forth. This rotation of sorts is enough of a variation to the cells to prevent them from accommodating to a constant stimulation by recurrent stimuli.

Applicant submits that claim 20 is additionally patentable over the cited references.

*Claim Rejections - 35 USC § 103*

*Zhang et al. as applied to claim 1 and 14, above, and further in view of Alvarez, "The healing of superficial skin wounds is stimulated by external current" and Doan et al. "In vitro effects of therapeutic ultrasound on cell proliferation, protein synthesis and cytokine production by human fibroblasts, and monocytes" and optionally Henley USPN 5,667,487*

The Examiner rejects claims 2 - 13, and 21 over Zhang et al. as applied to claim 1 and 14, above, and further in view of Alvarez, "The healing of superficial skin wounds is stimulated by external current" and Doan et al. "In vitro effects of therapeutic ultrasound on cell proliferation,

protein synthesis and cytokine production by human fibroblasts, and nomocytes" and optionally Henley USPN 5,667,487.

The Examiner states, "Zhang teaches the production of collagen as a method for healing skin and teaches the application of iontophoresis as well as ultrasound so as to provide a synergistic effect (column 4 - line 8 - 20). While he does not teach that the currents and the ultrasound employed would stimulate collagen, it is apparent from the Alvarez and the Doan references that currents and ultrasound in the energy ranges that provide iontophoriesis as well as phonophoresis also produce collagen healing. Thus, carrying out normal iontophoresis as well as ultrasound simultaneously (as additionally taught by Henley) would inherently result in collagen formation. In addition, it would be obvious to used the methods of Alvarez and Doan since they would provide the synergistic collagen formation that is desired by Zhang et al."

Claims 2 - 13 each depend, at least indirectly from independent claim 1, which is submitted to be patentable. Claim 21 depends from independent claim 14, which is submitted to be patentable. Applicant, therefore, submits that claims 2 - 13 and 21 are patentable for at least this reason.

Considering the foregoing, it is sincerely believed that this case is in a condition for allowance, which is respectfully requested.

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This paper is intended to constitute a complete response to the outstanding Office Action. Please contact the undersigned if it appears that a portion of this response is missing or if there

PATENT  
Attorney Docket No.: 88196/00-143  
USSN: 09/977,051  
Page 14

remain any additional matters to resolve. If the Examiner feels that processing of the application can be expedited in any respect by a personal conference, please consider this an invitation to contact the undersigned by phone.

Respectfully submitted,



**SIGNATURE OF PRACTITIONER**

9/22/03  
**DATE**

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